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ORIGINAL PAPER

Identification of prognostic factors for the nonoperative treatment of stiff shoulder

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Abstract
Purpose This study evaluated prognostic factors for the nonoperative treatment of stiff shoulder.
Methods Between June 2005 and May 2010, 497 stiff shoulders treated at our institute were included in this study. Multivariable analysis for recovery with Cox proportional hazard model was performed. The chief determining variable was pathogenesis (idiopathic, diabetic, post-traumatic) and confounding variables were age (49 or less, 50–59, 60 and above), sex, onset to visit interval (three months or less, four months or more), and external rotation (under 0°, 0° or more) or forward flexion (less than 90°, 90° or more) or internal rotation on the first visit.
Results There were 356 idiopathic, 61 diabetic, and 80 post-traumatic stiff shoulders. Hazard ratio (HR) and 95 % confidence interval (CI) for recovery (lower HR means poor prognosis) was 0.54 (0.36–0.96) in the diabetic group (p=0.007), and 0.92 (0.67–1.25) in the post-traumatic group (p=0.58) compared with the idiopathic group. A positive correlation was observed in ages of 60 or over (HR 1.46, 95 % CI 0.86–1.65, p-value 0.02) and external rotation under 0° on the first visit (0.71, 0.53–0.96, 0.03). No correlations were observed in sex (p=0.78) or onset to visit interval (p=0.99). Similar results were obtained when forward flexion or internal rotation was used as a confounding variable.
Conclusions Diabetes mellitus and severely restricted joint motion on the first visit were poor prognostic factors and ages of 60 or over was a better prognostic factor.

Level of evidence Treatment Study Level III (Retrospective comparative study).

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Introduction

Stiff shoulder is a common disease and disturbs the activities of daily living in the middle aged population. It affects females more often than males and typically develops in the fifth and sixth decades [1]. The prevalence of stiff shoulder in the general population has been reported to be 2–5 % [2]. The diagnosis of stiff shoulder is clinically made by pain, especially at night, and restricted active and passive motion in all planes [3]. Stiff shoulder is subdivided into idiopathic (primary) frozen shoulder and acquired (secondary) stiff shoulder [4]. Idiopathic frozen shoulder is a condition that shows global stiffness of the shoulder, which is caused by a capsular contracture without previous trauma or surgery [5]. Acquired stiff shoulder includes post-traumatic and post-surgery stiff shoulders [5]. Clinical features of stiff shoulder are divided into the freezing, frozen, and thawing phases, or stage 1, 2, 3, and 4 [6]. In stage 1, the patients present with pain and limited motion that is restored under anaesthesia. In the second stage (freezing phase) patients show pain with limited motion that is not restored under anaesthesia. The third stage (frozen phase) is characterised by mild or minimal pain with marked loss of motion. The fourth stage (thawing phase) patients show progressive improvement in limited motion.

Although some investigators have recommended benign neglect based on the fact that natural history of stiff shoulder is

self-resolving [7, 8], recent studies have reported less optimistic outcomes with residual pain and limited motion even after several years [3, 9]. Shaffer et al. reported persistence of symptoms and impaired range of motion especially in external rotation in over 50 % of cases at a seven-year follow-up [3]. Conservative treatment for stiff shoulder includes oral administration of non-steroidal anti-inflammatory drugs, oral administration or intra-articular injection of corticosteroid, and physiotherapy [2, 10–15]. During these treatment modalities, the efficacy of intra-articular injection of corticosteroid for patients in the freezing phase and that of physiotherapy for patients in the frozen phase are well described [12–14]. The efficacy of oral corticosteroid medication is also reported [2, 15]. Bulgen et al. demonstrated ineffectiveness of non-steroidal anti-inflammatory drugs for the freezing phase patients [10]. Approximately 90 % of patients with stiff shoulder respond well to intra-articular injection of corticosteroid and physiotherapy, and accordingly, surgical treatment is required in approximately 10 % of patients [8, 16].

Prognostic factors for the nonoperative treatment of stiff shoulder are diabetes mellitus, trauma at onset, duration of symptoms before treatment, sex, age, and severity of restricted joint motion [5, 10–12, 16–18]. Patients with diabetes mellitus show a higher incidence and bilateral involvement, and are recalcitrant to the conservative treatment compared to the non-diabetic patients [1, 17, 19]. Although corticosteroid injections may be beneficial, the deleterious effects of corticosteroids such as increased risk of bacterial infection and osteonecrosis of the humeral head should be considered. Post-traumatic stiff shoulder involves not only the glenohumeral joint capsule but also extra-articular structures and may show different responses to conservative treatment [5]. Some authors insist that longer symptom periods before treatment, men, younger age, and severely restricted joint motion on the first visit were risk factors of worse prognosis [11, 16, 18], while others do not [10, 12]. The purpose of this study was to examine the prognostic factors for the nonoperative treatment in patients with idiopathic, diabetic, and post-traumatic stiff shoulders.

Materials and methods

Selection criteria

Between June 2005 and May 2010, a total of 595 consecutive stiff shoulders in 571 patients treated at our institute were retrospectively evaluated in this study. The inclusion criteria were: (1) at least a one-month history of pain and stiffness; (2) restriction of passive glenohumeral motion of 100° of forward flexion or less, 20° of external rotation or less, and 5th lumber vertebra during internal rotation or less; and (3) normal radiological appearance [3, 4]. All patients had routine radiographic evaluation of anteroposterior views in internal rotation and external rotation, and outlet views of both shoulders. Patients with radiographic abnormalities such as glenohumeral osteoarthritis, calcific tendinitis, superiorly migrated humeral head, and osteonecrosis of the humeral head were excluded from this study. Magnetic resonance imaging was not undertaken routinely, but those with either muscle weakness or positive impingement sign were excluded because of a high suspicion of rotator cuff tear. Patients with pain persisting less than one month on their first visit were excluded because they might have had spontaneous recovery at the early stage. Of the 595 shoulders in 571 consecutive patients, 79 shoulders in 74 patients were excluded from the analysis because the patients discontinued coming to the clinic within a month. Nineteen shoulders with less severe symptoms in 19 patients affected bilaterally were also excluded from the study. Therefore, 497 shoulders (excluding 98 shoulders from 595 shoulders) were finally analysed in this study. Range of motion measurements, including forward flexion, external rotation in adduction, and internal rotation (measured by asking the patients to place the thumb to the highest possible spinous process), were measured with the patients in the standing position. History of diabetes mellitus and onset of pain (spontaneously or after trauma) were examined by self-questionnaire. Post-traumatic stiff shoulder was defined as the condition which developed after trauma without fracture or dislocation around the shoulder girdle. Falling was the cause in 56 out of 80 shoulders (70 %), traffic accident in ten shoulders (12.5 %), and other factors in 14 shoulders (17.5 %). Patients with a history of previous surgery around the shoulder were also excluded.

Treatment protocol

The patients presenting with pain at night and/or pain at rest, and sleep disturbance were considered to be in the freezing phase and treated with intra-articular injections of corticosteroid and local anaesthetic. A mixture of 4 mg of dexamethasone and 4 ml of 1 % lidocaine was injected into the glenohumeral joint via an anterior approach using anterior arthroscopic portal landmarks without fluoroscopy once a week until their symptoms were relieved. The patients with moderate or minimal pain at night and at rest were considered to be in the frozen phase and physiotherapy was initiated. Physiotherapy was continuously performed with assistance of a physical therapist. Relaxation of the muscles around the shoulder girdle and passive and active-assisted exercises were initiated avoiding provocation of pain. Stretching of the muscles around the thorax, spine, trunk, and hip joints was also performed. Surgical intervention was considered in cases where the range of motion was still limited and was not sufficient for their activities of daily living after at least three months of physiotherapy.

Outcome assessment

The baseline items of the patients to be assessed were aetiology (idiopathic, diabetic, and post-traumatic), gender, age, time from onset to visit, range of motion on the first visit, and disease phase (freezing and frozen phases). The number of injections in the freezing phase, time from visit to recovery, and percentage of patients who eventually underwent surgery were also analysed. Data were expressed as percentage, mean (standard deviation), or median (interquartile range). Fisher's exact test was used for sex, operative cases, and internal rotation on the first visit. Kruscal-Wallis test was used for age, onset to visit interval, forward flexion and external rotation on the first visit, the number of injections, and visit to recovery interval. The recovery was defined when the patients regained motion within 15° of the contralateral side in both forward flexion and external rotation as well as within three spinal levels of the contralateral side for internal rotation [20]. There were no patients with functional limitation after they achieved the definition of recovery. When motion over 160° of forward flexion, 45° of external rotation, and 10th thoracic spinous level of internal rotation was achieved, it was considered as recovery for patients with bilateral shoulder involvement.

Following evaluation of the baseline items and clinical results of the conservative treatment, the data was analysed in an adjusted fashion using Kaplan-Meier survivorship curves and the Cox proportional hazards multivariable analysis. The chief determining variable was pathogenesis (idiopathic, diabetic, and post-traumatic), and confounding variables were age (less than 49, 50–59, 60 or over), sex, interval between onset to first visit (three months or less, four months or more), and external rotation on the first visit (under 0°, 0° and above) or forward flexion on the first visit (under 90°, 90° and above) or internal rotation on the first visit (5th lumber vertebra, sacrum or buttock or greater trochanter). Surgically treated cases were considered as censored at the time of operation. Patients who discontinued visiting by themselves were considered as censored at the time of final visiting. Our survivorship analysis was designed to determine which variables reached "recovery" first, therefore, a hazard ratio less than 1 or a survivorship curve to the right of the others was considered as more resistant to the conservative treatment. The magnitudes of associated risk factors to the conservative treatment were presented as a hazard ratio and a 95 % confidence interval. All statistical analyses were two-sided, and $P<0.05$ was accepted as statistically significant. All statistical analyses were performed using the R version 2.13.0.

Results

Baseline characteristics of stiff shoulders according to pathogenesis are shown in Table 1. There were 356 idiopathic frozen shoulders (72 %), 61 diabetic frozen shoulders (12 %), and 80 post-traumatic stiff shoulders (16 %). Women were predominant in idiopathic frozen shoulders and post-traumatic stiff shoulders, and men were predominant in diabetic frozen shoulders ($p<0.001$). No disparity was found among the three groups concerning age ($p=0.47$), onset to visit interval ($p=0.07$), forward flexion ($p=0.96$), external rotation ($p=0.59$), and internal rotation ($p=0.83$) on the first visit.

A flowchart illustrating treatment protocols and the number of shoulders is shown in Fig. 1. On their first visits, 384 shoulders (77 %) were in the freezing phase and 113 shoulders (23 %) were in the frozen phase. Two hundred seventy-six shoulders were assessed as "recovery" after conservative treatment, whereas 28 shoulders (5.6 %) were treated surgically after failed conservative treatment. The rest of the193 shoulders were unable to be assessed because the patients discontinued visiting before reaching "recovery". Clinical results of conservative treatment according to pathogenesis are shown in Table 2. The median number of injections in freezing patients on the first visit (384 shoulders) was five times in the three groups ($p=0.91$). The median times from the first visit to recovery in patients where "recovery" was confirmed (276 shoulders) were ten months in idiopathic, 12 months in diabetic, and ten months in post-traumatic stiff shoulders ($p=0.09$). Mean times from the first visit to recovery were 10.7± 4.6 months in the freezing phase patients on the first visit and 10.8±5.7 months in the frozen phase patients ($p=0.88$). Operative cases were 17 shoulders (4.8 %) in idiopathic, four shoulders (6.6 %) in diabetic, and seven shoulders (8.8 %) in post-traumatic stiff shoulders ($p=0.32$). No adverse effects such as bacterial infection and osteonecrosis of the humeral head were observed during the study period.

A hazard ratio (HR) and 95 % confidence interval (CI) for recovery with Cox proportional hazards multivariable analysis are shown in Table 3. Age 49 years or less, women, early visit (three months or less), fair restriction of external rotation (0° or less) or forward flexion (90° or less) or internal rotation (5th lumber vertebra), and idiopathic frozen shoulders were set as references. A HR and 95 % CI in age 60 and below were 1.46 and 1.05–2.01 (better prognosis) and statistically significant differences were observed ($p=0.02$). No significant differences were observed between women and men ($p=0.78$), and between early visit and late visit groups ($p=0.99$). A HR and 95 % CI in severely restricted external rotation (less than 0°) on the first visit were 0.71 and 0.53–0.96 (worse prognosis) ($p=0.03$), respectively. Though statistically significant differences were observed between idiopathic and diabetic groups ($p=0.007$), there were no differences between idiopathic and post-traumatic groups ($p=0.58$). Similar results were obtained when forward flexion or internal rotation was used as a confounding variable (data were not shown). Results of Kaplan-Meier survivorship curves of idiopathic, diabetic, and post-traumatic stiff shoulders are shown in Fig. 2. This

Table 1 Baseline characteristics of stiff shoulders according to the type of pathogenesis

Characteristic	Idiopathic (*N*=356)	Diabetic (*N*=61)	Post-traumatic (*N*=80)	*p*-value
Men (%)	37 %	69 %	33 %	*< 0.001*
Age, mean (SD)	57.4 (8.9)	58.7 (10.0)	58.2 (9.3)	0.47
Onset to visit interval (months), median (IQR)	5 (3 – 8)	6 (4 – 9)	5 (3 – 8)	0.07
FF on the first visit, median (IQR)	90 (85–100)	90 (85–100)	90 (85–100)	0.96
ER on the first visit, median (IQR)	5 (0 – 10)	0 (−5 – 10)	5 (0 – 10)	0.59
IR on the first visit, median (IQR)	S (S-B)	S (S-B)	S (S-B)	0.83

SD standard deviation, *IQR* interquartile range, *FF* forward flexion, *ER* external rotation, *IR* internal rotation, *S* sacrum, *B* buttock

analysis also confirmed that diabetic frozen shoulders showed the worst prognosis among the three groups.

Discussion

A total of 497 consecutive patients with stiff shoulder treated with intra-articular injections of corticosteroid and physiotherapy were evaluated retrospectively in this study. Two hundred and seventy-six patients recovered after conservative treatment and 28 shoulders were treated surgically after failed conservative treatment, whereas 193 patients discontinued visiting before reaching "recovery". The findings of this study indicated that patients with diabetes mellitus and external rotation under 0° on the first visit responded worse to the conservative treatment. On the other hand, patients aged 60 years or over responded well to the treatment. Sex, onset to visit interval, and predisposing trauma at onset did not affect the clinical results.

We attempted to identify the variables that have prognostic importance for the treatment of stiff shoulder and the study

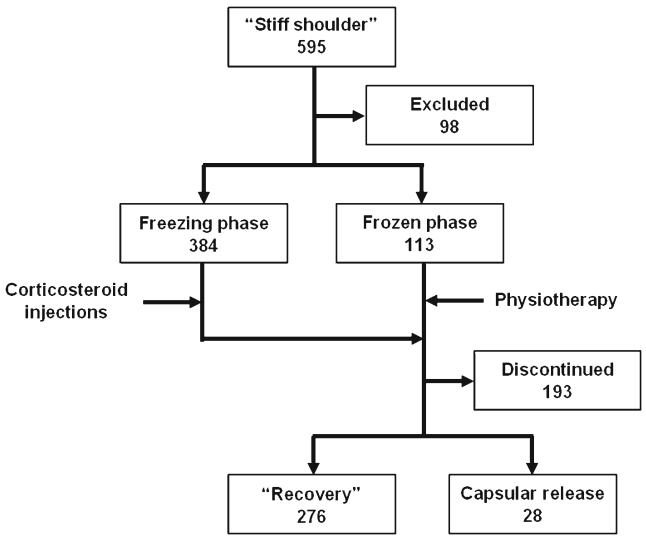

Fig. 1 Flowchart illustrating treatment protocol and the number of shoulders

identified several factors associated with the prognosis. Hazleman et al. reported that a successful treatment was dependent on duration of the symptoms [18]. From the onset of the symptoms, patients treated within two to five months recovered in 8.1 months, and patients treated within six to 12 months required 14 months for recovery. We postulated that a prolonged period of symptoms would cause more severe capsular fibrosis, which would lead to a much longer time for recovery, but we did not find any differences between the early and late visit groups in this study. Some authors have reported that men, younger age, and severely restricted range of motion on the first visit were risk factors of worse clinical results [3, 11, 16]. On the other hand, other authors insist that the severity of the condition has no correlation with eventual recovery [10, 12]. In this study, it was found that severely restricted joint motion on the first visit was associated with poor prognosis, aged 60 or older with better prognosis, but sex had no correlation with the prognosis.

Patients with diabetes mellitus responded worse to the conservative treatment in this study, which was in line with the previous studies [9, 16, 19]. It was difficult to know the precise mechanism of worse prognosis in diabetes mellitus, but excessive glucose concentration might lead to a faster rate of collagen glycosylation and cross-linking of collagens, which might restrict the shoulder motion [21]. Further, a recent study indicated that chondrogenic changes of the capsule were observed in patients with recalcitrant idiopathic frozen shoulder [22]. Therefore, the association between recalcitrant idiopathic frozen shoulder and cross-linking and the chondrogenic process of the capsule must be examined in a future study. The potential disadvantages of corticosteroids should be considered, especially in patients with diabetic frozen shoulder, and injections of those agents must be done with circumspection. In this study, there were no severe complications such as bacterial infections and osteonecrosis of the humeral head. Post-traumatic stiff shoulder was defined as a limitation of the shoulder movement after an injury without fracture and dislocation around the shoulder girdle because post-fracture or post-operative stiff shoulder was an entirely different condition [5]. Hand et al. reported that a predisposing

Table 2 Clinical results of conservative treatment according to the type of pathogenesis

Result	Idiopathic	Diabetic	Post-traumatic	*p*-value
Number of injections[a], median (IQR)	5 (3 – 7)	5 (3 – 7)	5 (4 – 6)	0.91
Visit to recovery (months)[b], median (IQR)	10 (7 – 13)	12 (9 – 15)	10 (9 – 12)	0.09
Operative cases, *N* (%)	17 (4.8 %)	4 (6.6 %)	7 (8.8 %)	0.32

IQR interquartile range

[a] Data were analysed in freezing phase patients on the first visit (384 shoulders)

[b] Data were analysed in patients who continued visiting until recovery (276 shoulders)

minor trauma at the onset did not influence the final outcome [1]. This study also demonstrated that stiff shoulder could be successfully managed irrespective of a previous trauma history such as a fall or traffic accident. Associations between idiopathic frozen shoulder and systemic diseases such as thyroid diseases, myocardial infarction, and cerebrovascular accidents are reported [17, 23]. In this study, we examined these diseases by self-questionnaire but no patients declared them.

The median time to recovery was 10–12 months and operative cases were 4.8 to 8.8 % in this study, which were superior or equivalent to the previous reports. The type of corticosteroid, the dosage, and frequency of the injection vary from study to study [10, 12, 14]. The injections of 4-mg dexamethasone were conducted once a week in this study until pain was relieved, which had the effect of reducing synovial inflammation and subsequent capsular fibrosis and allowed improvement of motion with a decreased time to functional recovery [24]. It was reported that physiotherapy alone improved shoulder function [11], but Rizk et al. noted that only 60 % of their patients with physiotherapy alone achieved the ability to sleep pain-free after five months of treatment [25]. Hazleman et al. described that 33 % of their patients reported increased pain after physiotherapy without former pain control [18]. The physiotherapy in this study was standardised proprioceptive neuromuscular facilitation and range of motion exercises by the physiotherapists followed by active exercises with gym equipment once a week until "recovery" was confirmed. Approximately 40 % of patients (193 out of 497 patients) discontinued visiting our clinic during the rehabilitation periods in this study. Mean time from the first visit to the discontinuation in the 193 patients was approximately eight months (data not shown), and most of the patients regained sufficient shoulder motion and function before we confirmed the "recovery" despite some degree of restricted range of motion in these patients.

It is difficult to define "recovery" in patients with stiff shoulders and there is no gold standard to determine "recovery". Historically, frozen shoulder has been regarded as a benign and self-limited condition [7, 8]. However, several investigators have reported that (1) many patients had measurable differences in the range of motion between the affected and unaffected shoulders and (2) abnormal shoulder function occurred despite the success of treatment and patient's satisfaction even after a few years [3, 11, 16]. These findings indicated that completely normal motion and

Table 3 Hazard ratio and 95 % confidence interval for recovery; results of multivariable analysis

Variable	HR	95 % CI	*p*-value
Aged<49	1.00	Reference	–
Aged 50–59	1.19	0.86–1.65	0.28
Aged ≥60	1.46	1.05–2.01	*0.02*
Women	1.00	Reference	–
Men	1.04	0.80–1.34	0.78
Early visit (≤3 months)	1.00	Reference	–
Late visit (≥4 months)	1.00	0.77–1.30	0.99
ER fair restricted (≥0°)	1.00	Reference	–
ER poor restricted (<0°)	0.71	0.53–0.96	*0.03*
Idiopathic	1.00	Reference	–
Diabetic	0.54	0.36–0.81	*0.007*
Post-traumatic	0.92	0.67–1.25	0.58

Lower hazard ratio indicates more resistant to the conservative treatment. Values in italics represent statistical significance

HR hazard ratio, *CI* confidence interval, *ER* external rotation

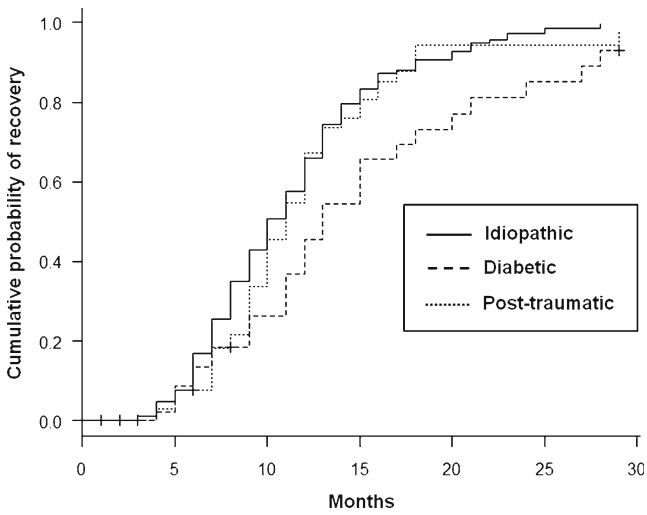

Fig. 2 Results of Kaplan-Meier survivorship curves

function of the shoulder is not a prerequisite for patient satisfaction. We felt the criteria proposed by Marx et al. as clinically acceptable and used them for evaluation in this study [20].

There are several limitations in this study. Firstly, this study was a retrospective study and loss of follow-up rates were high (approximately 40 %). Moreover, presence of diabetes mellitus was determined by self-questionnaire, and diabetic status (medication, injection of insulin, or diet therapy) was not included. Furthermore, levels of blood sugar and haemoglobin A1c were not examined. Because there is no clear definition of stiff shoulder by objective tests or imaging, there remains a possibility that some patients have alternative shoulder disorders such as a rotator cuff tear. Another limitation of this study was that treatment modalities for patients in the freezing phase might not be well accepted. Four milligram dexamethasone once a week until relief of pain might be draconian and it was impossible to know for certain that all injections were indeed intra-articular [13]. However, the pain dramatically decreased after the injections and we had no complications such as infection and osteonecrosis of the humeral head.

Conclusions

Prognostic risk factors for nonoperative treatment of stiff shoulder were examined. Patients with diabetes mellitus and severely restricted joint motion on the first visit responded worse to conservative treatment. On the other hand, patients aged 60 years or over responded well to the treatment.

Conflict of interests The authors declare that they have no conflict of interest.

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